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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/815,198

03/25/2004

William A. Palmisano

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8645

5179 7590 12/10/2008

PEACOCK MYERS, P.C.  
201 THIRD STREET, N.W.  
SUITE 1340  
ALBUQUERQUE, NM 87102

EXAMINER

HARRIS, ALANA M

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

12/10/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/815,198	<b>Applicant(s)</b> PALMISANO ET AL.	
	<b>Examiner</b> Alana M. Harris, Ph.D.	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 3,7 and 10-13 is/are pending in the application.
- 4a) Of the above claim(s) 7,12 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3, 10 and 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/10/2008</u>  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Response to Arguments***

1. Claims 3, 7 and 10-13 are pending.

Claims 7, 12 and 13, drawn to non-elected inventions are withdrawn from examination.

Claims 3, 10 and 11 are examined on the merits.

***Maintained Grounds of Rejections***

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The rejection of claims 3, 10 and 11 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication number 2005/0069924 A1 (effective filing date February 23, 2001), and further in view of Palmisano et al. (Cancer Research 60: 5954-5958, November 1, 2000/ IDS reference listed on sheet 4, submitted July 19, 2004) and WO 02/00927 A2 (effective filing date July 2, 2001) is maintained.

Applicants assert the publication (referenced as Goggins in the Remarks) does not correspond to the PAX5  $\beta$  gene promoter, see Remarks submitted September 10, 2005, page 5, 4th paragraph. Applicants note SEQ ID NO: 7 of the publication is remote from the promoter region of PAX5  $\beta$ , hence publication '9924 cannot be used as

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a teaching to determine the methylation state of the promoter region of the PAX5  $\beta$  gene claimed by Applicants, see bridging paragraph of pages 5 and 6 of the Remarks.

Applicants conclude arguments noting the secondary references fail to remedy the deficiency of the publication, see Remarks, page 6, 1st full paragraph. These points of view and arguments have been carefully considered, but found unpersuasive.

While the publication may not explicitly teach the PAX5  $\beta$  gene that does not preclude the instant rejection. The publication teaches nucleic acid-containing specimen taken from a subject which may still contain the portion of the PAX5  $\beta$  gene where the promoter methylation resides. Implementation of the second stage methylation-specific PCR reaction, as well as primers, SEQ ID NO: 3 and SEQ ID NO: 4 taught in the secondary references would still be able to yield a valid assessment of monitoring for cancer in a biological specimen to detect the presence of inactivation of the PAX5  $\beta$  gene. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the claimed invention was made to implement the teachings of all the references to assay the biological specimen using the assay conditions and reagents dictated by the references to critically analyze the methylation status. It remains the primers will inextricably amplify a product if the target sequences are present in the specimen. It is obvious from the publication it teaches a method of monitoring cancer in the biological specimen included a PCR reaction and amplification methylated templates under a higher annealing temperature, see page 12, section 0097; page 13, section 0099; and page 14, sections 0104 and 0105. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by

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references, see entirety of all documents. For the reasons of record and the analysis set forth the rejection is maintained.

4. The rejection of claims 3, 10 and 11 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication number 2005/0069924 A1 (effective filing date February 23, 2001), and further in view of WO 02/00927 A2 (effective filing date July 2, 2001) is maintained.

Applicants assert the publication (referenced as Goggins in the Remarks) does not correspond to the PAX5  $\beta$  gene promoter, see Remarks submitted September 10, 2005, page 5, 4th paragraph. Applicants note SEQ ID NO: 7 of the publication is remote from the promoter region of PAX5  $\beta$ , hence publication '9924 cannot be used as a teaching to determine the methylation state of the promoter region of the PAX5  $\beta$  gene claimed by Applicants, see bridging paragraph of pages 5 and 6 of the Remarks. Applicants conclude arguments noting the secondary reference fails to remedy the deficiency of the publication, see Remarks, page 6, 1st full paragraph. These points of view and arguments have been carefully considered, but found unpersuasive.

While the publication may not explicitly teach the PAX5  $\beta$  gene that does not preclude the instant rejection. The publication teaches nucleic acid-containing specimen taken from a subject which may still contain the portion of the PAX5  $\beta$  gene where the promoter methylation resides. Implementation of the second stage methylation-specific PCR reaction, as well as primers, SEQ ID NO: 3 and SEQ ID NO: 4 taught in the secondary references would still be able to yield a valid assessment of

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### ***Conclusion***

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, Monday through Saturday with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Alana M. Harris, Ph.D.  
25 November 2008

/Alana M. Harris, Ph.D./

Primary Examiner, Art Unit 1643